IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AZURITY PHARMACEUTICALS, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 21-1286 (MSG)
	)	C.A. No. 21-1455 (MSG)
BIONPHARMA INC.,	)	
	)	
Defendant.	)	

JOINT SUBMISSION REGARDING PROPOSED SCHEDULE

Pursuant to the Court's February 7, 2023 Order (D.I. 261, C.A. No. 21-1286 and D.I. 165, C.A. No. 21-1455), below is a table reflecting Plaintiff Azurity Pharmaceuticals, Inc.'s ("Azurity") and Defendant Bionpharma Inc.'s ("Bionpharma") respective proposed schedules for all remaining case deadlines. Beneath the table are the parties' respective brief explanations in support of their proposed schedules.

Event	Prior Deadline	Azurity's Proposal	Bionpharma's Proposal
Deadline for Bionpharma to Move for Summary Judgment on Azurity's Patent Claims	--	N/A	March 20, 2023
Deadline for Azurity's Opposition to Motion for Summary Judgment	--	N/A	April 3, 2023
Deadline for Bionpharma's Reply in Support of Motion for Summary Judgment	--	N/A	April 10, 2023
Substantial Completion of Document Production	September 12, 2022	N/A	August 7, 2023
Close of Fact Discovery	December 12, 2022	May 5, 2023	December 15, 2023
Opening Expert Reports for Issues on which Party Bears Burden of Proof	January 16, 2023	June 9, 2023	February 12, 2024
Responsive Expert Reports	March 6, 2023	July 28, 2023	April 12, 2024
Reply Expert Reports	April 10, 2023	N/A	May 16, 2024

Event	Prior Deadline	Azurity's Proposal	Bionpharma's Proposal
Status Conference (to Discuss Bifurcation of Daubert & Dispositive Motion Practice and Trial)	--	Week of August 7-11, 2023 (At the Court's Convenience)	N/A
Close of Expert Discovery	June 26, 2023	September 8, 2023	August 2, 2024
Deadline to File Daubert Motions (Oppositions & Replies due per D. Del. LR 7.1.2(b))	July 17, 2023	September 29, 2023	August 23, 2024
Deadline to File Case-Dispositive Motions (Oppositions & Replies due per D. Del. LR 7.1.2(b))	August 21, 2023	September 29, 2023	September 13, 2024
Hearing on Daubert and Case-Dispositive Motions	October 10, 2023	November __, 2023	October 29, 2024, or at the Court's convenience
Deadline to File Joint Proposed Final Pretrial Order	December 4, 2023	January 12, 2024	December 20, 2024
Pretrial Conference	December 19, 2023	February __, 2024	January 13, 2025, or at the Court's convenience
Trial	February 1, 2024	March __, 2024	March 3, 2025, or at the Court's convenience

Azurity's Statement in Support of Proposed Schedule:[1]

Azurity's paramount concern remains getting to trial as quickly as possible, so as to—if Azurity is ultimately successful—enjoin Bionpharma's infringing generic product, which has been wrongfully on the market for 18 months, all the while eroding Azurity's market share. Azurity's proposed schedule accomplishes this goal, while largely adhering to the timing set

[1] All "D.I." citations are to the docket in C.A. No. 21-1286.

forth in the current Scheduling Order (D.I. 126). Accordingly, Azurity respectfully requests that its proposed schedule be adopted.

First, with respect to dates following the Close of Fact Discovery: Azurity's proposed schedule largely adheres to the timing contemplated in the current Scheduling Order (D.I. 126). More specifically, the only differences are as follows:

- Azurity has deleted the deadline for Reply Expert Reports. The Court issued a similar schedule in one of the related cases. *See Azurity Pharms., Inc. v. Annora Pharma Private Ltd.*, C.A. No. 21-196 (D. Del. May 9, 2022), D.I. 131 at 2. Although having two rounds of expert reports rather than three requires additional work from the patentee initially (as secondary considerations of non-obviousness must be addressed in Opening Reports), Azurity is willing to undertake this work in exchange for an earlier trial date.

- Pursuant to the Court's suggestion that bifurcation of the patent and antitrust claims be revisited once discovery is over (D.I. 262 at 12:14-13:6), Azurity has proposed a status conference for that purpose following completion of expert reports.

- The current Scheduling Order allots eleven weeks between final expert reports (April 10, 2023) and the Close of Expert Discovery (June 26, 2023). Azurity respectfully submits that this time period can be shortened to six weeks (July 28, 2023 to September 8, 2023) and still afford ample time in which to complete expert depositions.

- Azurity has combined the deadlines to file *Daubert* Motions and Case-Dispositive Motions, as is often done. *E.g.*, *Azurity Pharms., Inc. v. Annora Pharma Private Ltd.*, C.A. No. 21-196 (D. Del. May 9, 2022), D.I. 131 at 2. Indeed, given that the current Scheduling Order contemplates a combined page limit and joint hearing for both motions (D.I. 126 at ¶¶ 16(b)-(c)), it would be simpler to have the deadlines aligned.

Second, with respect to the Close of Fact Discovery: Azurity respectfully submits that May 5, 2023—which is four months[2] after discovery re-opened—is sufficient time in which to complete any remaining discovery. This is so for the following reasons:

- The current Scheduling Order allotted 10.5 months to complete fact discovery—from January 27, 2022 (the date of the Scheduling Order) until December 12, 2022 (the Close

[2] On December 7, 2022, the Court stayed discovery "pending disposition of Plaintiff's Motion to Dismiss and Defendant's Motion for Judgment on the Pleadings." D.I. 250, ¶ 3. Those motions were resolved on January 11, 2023 (D.I. 256) and January 6, 2023 (D.I. 254). Accordingly, the case resumed on January 11, 2023.

of Fact Discovery). Bionpharma's proposed schedule provides for even more time—i.e., from January 11, 2023 (when discovery re-opened) to December 15, 2023 (Bionpharma's proposed Close of Fact Discovery). Bionpharma's proposal ignores that the parties have already completed significant discovery in this case. Azurity's four-month proposal accounts for the fact that significant discovery has already taken place, and should provide sufficient time to complete any remaining discovery.

- Patent Discovery: As Azurity has previously explained, patent discovery is largely complete. D.I. 238 at 3-4. Depositions are the main item yet to be accomplished. *Id.* at 4. And the only pending discovery disputes involve discovery that Azurity is seeking from Bionpharma. *Id.* Azurity respectfully submits that both issues can be resolved well-within the time between now and May 5, 2023.

- Antitrust Discovery: There remains antitrust discovery to be completed (although some of the "patent discovery" will be relevant to both issues) because the parties mutually held antitrust discovery in abeyance for five months (from May 2022 until October 2022) while Azurity's motion to stay antitrust discovery was pending. *Id.* at 6-7. When Bionpharma sought to resume antitrust discovery on October 3, 2022, Azurity promptly moved forward with such discovery. *Id.* at 7-8. Azurity respectfully submits that all remining antitrust discovery can be completed by May 5, 2023. This is reinforced by the fact that the time remaining until May 5, 2023 matches the time that was remaining to complete fact discovery when Bionpharma proposed resuming antitrust discovery last year (i.e., from October 3, 2022 until December 12, 2022).

- Azurity has been proceeding diligently to complete fact discovery. For example, Azurity has noticed seven depositions to Bionpharma and its personnel,[3] and does not presently intend to notice any others (D.I. 209; D.I. 220; D.I. 224; D.I. 225; D.I. 226; D.I. 227; D.I. 228), and Azurity's patent discovery disputes have been briefed and are ripe for resolution (D.I. 240; D.I. 241). And when Bionpharma last year indicated the need to resume antitrust discovery, Azurity promptly proceeded with the discovery the parties had been holding in abeyance. Bionpharma, in contrast, then changed course and instead sought a stay (D.I. 238 at 7-8), and has yet to notice any depositions. Further, Bionpharma has yet to seek any of the additional discovery it allegedly needs despite discovery re-opening on January 11, 2023. In short, Bionpharma is not making an effort to promptly complete discovery while requesting a lengthy extension of the case schedule.

Third, with respect to Bionpharma's proposed dates for Summary Judgment briefing and the Substantial Completion Deadline: Azurity respectfully submits that these dates are unnecessary. Specifically:

[3] For completeness, Azurity has also sought seven non-party depositions via Rule 45 subpoena.

- Should Bionpharma wish to submit an early summary judgment motion with respect to Azurity's patent claims, it can do so pursuant to the terms of the current Scheduling Order. D.I. 126 at ¶ 16(a). Further, given Bionpharma's position that the patent and antitrust discovery is "completely overlapping" (D.I. 262 at 8:25-9:1, 9:9-10), there is no economy to be gained in delaying discovery while Bionpharma's summary judgement motion (should it file one) is pending. Additionally, this will be Bionpharma's fourth case-dispositive motion, having tried unsuccessfully on three previous occasions to dispose of the patent infringement claims (D.I. 87; D.I. 124; D.I. 254). The patents asserted against Bionpharma are not the same as those asserted in *Azurity Pharmaceuticals, Inc. v. Alkem Laboratories Ltd.*, C.A. No. 19-2100, and each claim of each patent "shall be presumed valid independently of the validity of other claims." 35 U.S.C. § 282.[4]

- Document production is already substantially complete. To wit, Azurity has produced over 121,000 pages of documents; Bionpharma has produced over 40,000 pages of document; and non-party CoreRx, Inc., Bionpharma's former supplier, has produced over 58,000 pages of documents. D.I. 238 at 3. To the extent any additional document production remains, Azurity respectfully submits that it can be accomplished in the time remaining for fact discovery without the need for any additional deadline.

In sum, Azurity's proposed schedule allows for a reasonable time in which to complete fact discovery, then largely adheres to the timing set forth in the current Scheduling Order for remaining dates. This balances Azurity's concern in obtaining a prompt trial date with Bionpharma's concern in having sufficient time to complete discovery. Azurity respectfully requests that the Court adopt Azurity's proposed schedule.

Bionpharma's Statement in Support of Proposed Schedule:

I. INTRODUCTION

Bionpharma respectfully submits that circumstances in these cases have materially changed since the February 7, 2023 Status Conference. *See* D.I.[5] 258, 261. Specifically, on February 10, 2023, this Court entered a judgment of invalidity in the related Alkem case[6] based

[4] As the Court requested a short explanation of the schedule, Azurity will not elaborate at this time, but will properly respond to any allegations in the appropriate briefing.

[5] All "D.I." references shall be to the 21-1286-MSG docket unless otherwise specified.

[6] *Azurity Pharm., Inc. v. Alkem Labs. Ltd.*, C.A. No. 19-2100-MSG (D. Del.).

on findings that the asserted claims from U.S. Patent Nos. 10,786,482 ("'482 patent) and 10,918,621 ("'621 patent")[7] are invalid as being obvious and lacking sufficient written description. Alkem case D.I. 213, Order; Alkem case D.I. 214, Mem. Op. Because, as explained below, the patent claims this Court found invalid in the Alkem case are subsumed within the asserted patent claims in the instant suits ("Third Wave Suits"), this Court's judgment of invalidity in the Alkem case collaterally estops Azurity from contesting the invalidity of the asserted patent claims in these Third Wave Suits. Bionpharma therefore respectfully requests leave to dispose of Azurity's patent infringement claims via a summary judgment motion limited solely to the issue of collateral estoppel based on this Court's decision in the Alkem case. Bionpharma should not be required to wait until the conclusion of discovery in these Third Wave Suits—after spending hundreds of thousands of dollars and countless hours engaging in discovery for invalid patent claims—especially because Azurity has been using its invalid patent claims in these cases to harass Bionpharma and its suppliers, and to damage Bionpharma's commercial relationships, as explained further below.

Furthermore, as is evident from the table set forth above, the parties have radically divergent views on the duration of the schedule in these cases. As explained further below, Bionpharma respectfully submits that Azurity's proposal is a non-serious one that should be rejected, including because (1) it ignores the fact that the parties have not yet exchanged ***any***

[7] The '482 and '621 patents, along with U.S. Patent No. 10,772,868 ("'868 patent"), are what Bionpharma has referred to in prior briefing as the "Second Wave Patents." *See* D.I. 187, Bionpharma's Rule 12(c) Mot. Reply Br. at Table of Abbreviations. Azurity asserted the Second Wave Patents against Bionpharma in late 2020 in connection with Civil Action No. 20-1256 ("Second Wave Suit"), but that suit was ultimately dismissed because Azurity could not prove infringement after Judge Stark issued His Honor's opinion and judgment of non-infringement in Civil Action Nos. 18-1962 and 19-1067 ("First Wave Suits"). 20-1256 D.I. 49, Second Am. Compl.; 20-1256 D.I. 106, Stipulation of Dismissal; D.I. 152, Joint Status Report at 2-3.

antitrust discovery in these cases, (2) the parties still have ample patent discovery to exchange should Azurity be allowed to continue with its invalid patent claims, and (3) Azurity's suit against Bionpharma's current ANDA product supplier (Novitium) just recently was transferred here (C.A. No. 23-163-MSG, "the Novitium suit") and should be consolidated with the instant Third Wave Suits (requiring additional fact discovery time). Finally, Azurity's proposal that expert reports should be limited to two rounds—contrary to what Judge Stark ordered in the original Scheduling Order (*see* D.I. 126 at 8)—is an attempt to undermine Bionpharma's invalidity defenses that should be rejected.

II. BIONPHARMA'S PROPOSED SCHEDULE SHOULD BE ADOPTED

A. Bionpharma Should Be Granted Leave to File for Summary Judgment on the Limited Issue of Collateral Estoppel

On February 10 in the Alkem case, this Court found that enalapril liquids preserved with only parabens that are stable for at least 12 months at refrigerated conditions are not described in the specification of the '482 and '621 patents, which share the same specification with the Third Wave Patents[8] asserted in the instant suits. D.I. 259, Azurity's Answer ¶ 126. Like Alkem's ANDA product, Bionpharma's ANDA product is preserved with only parabens (18-1962 D.I. 257, Op. at 8; 19-2100 D.I. 213, Mem. Op. at 50 n.25), and the claims that Azurity asserts from the Third Wave Patents[9] against Bionpharma all cover enalapril liquids preserved with parabens that are stable for at least 12 months at refrigerated conditions—liquids this Court found in the Alkem case are not described in the Third Wave Patents' common specification. *Juno*

[8] U.S. Patent Nos. 11,040,023 ("'023 patent") and 11,141,405 ("'405 patent"). *See* D.I. 89-1, First Am. Compl. Ex. A; 21-1455 D.I. 1-1, Compl. Ex. A.

[9] Azurity asserts against Bionpharma claims 1-6, 10-16, and 19 of the '023 patent, and claims 1-2, 6-7, 10, 12-14, 17, 19-20, and 22 of the '405 patent. *See* Ex. B-1, Azurity's Initial Infringement Claim Charts at 3 (Exhibits A and B thereto omitted).

Therapeutics, Inc. v. Kite Pharma, Inc., 10 F.4th 1330, 1336 (Fed Cir. 2021) ("[P]atent's written description [must] sufficiently demonstrate[] that the inventors possessed the full scope of the claimed invention."). Azurity is thus estopped in these cases from challenging the invalidity of the asserted claims of the Third Wave Patents for lack of written description. *See Ohio Willow Wood Co. v. Alps S., LLC*, 735 F.3d 1333, 1342 (Fed. Cir. 2013) ("Collateral estoppel protects a party from having to litigate issues that have been fully and fairly tried in a previous action and adversely resolved against a party-opponent.").

Similarly, in the Alkem case this Court found that the asserted '482 and '621 patent claims, which are subsumed within many of the asserted claims of the Third Wave Patents, are obvious over the prior art. As an example, claim 18 of the '621 patent, which this Court found obvious, is essentially subsumed within asserted '023 patent claims 1-3, 10, and 13-15[10] and asserted '405 patent claims 1-2, 12-14, 19, and 22, rendering those claims obvious.[11] Furthermore, the asserted dependent claims add limitations that this Court already found in the prior art and would be obvious to use in connection with an enalapril liquid with long-term stability—*e.g.*, a pH of about 3.3 (for asserted '023 patent claims 4-5), about 1 mg/mL of a paraben or mixture of parabens (for asserted '023 patent claims 16 and 19 and asserted '405

[10] Although the claims of the '023 patent do not expressly recite a buffer, Azurity has conceded that they include within their scope buffered enalapril liquids. D.I. 52-5, Reply Buckton Decl. ¶ 18; D.I. 52, Azurity's TRO/PI Reply Br. at 10 n.7 (conceding that Epaned®—which includes a buffer (18-1962 D.I. 257, Op. at 6)—is an embodiment of the '023 patent claims).

[11] It matters not that the asserted '023 and '405 patent claims include within their scope buffer-less enalapril liquids, as "[w]hen a patent claims a genus, an invention is obvious if a single embodiment falling within the scope of the claims is obvious." *Abbott GmbH v. Centocor Ortho Biotech, Inc.*, 971 F. Supp. 2d 171, 182 (D. Mass. 2013) (citing *Aventis Pharma Deutschland GmbH v. Lupin, Ltd.*, 499 F.3d 1293, 1300 (Fed. Cir. 2007)); *see also* Alkem case, D.I. 213, Mem. Op. at 4-5, 40 (finding claim 4 of the '621 patent—which covers stable enalapril liquids with a range of buffers, including citrate—obvious because the prior art rendered obvious stable enalapril liquids using citrate buffers).

patent claims 10 and 20), about 1 mg/mL of enalapril maleate (for asserted '023 patent claim 12 and asserted '405 patent claims 7 and 17). Alkem case D.I. 213, Mem. Op. at 22-23, 36-37. Azurity is thus collaterally estopped from contesting the obviousness of the asserted claims of the Third Wave Patents, and Bionpharma should be granted leave to file for summary judgment on claim preclusion grounds. *Ohio Willow*, 735 F.3d at 1342 ("Our precedent does not limit collateral estoppel to patent claims that are identical. Rather, it is the identity of the issues that were litigated that determines whether collateral estoppel should apply.").

1. Bionpharma Should Not Have to Wait Until the Close of Discovery to Raise Collateral Estoppel by Motion

Any argument from Azurity that leave for Bionpharma to file for summary judgment should be denied because Azurity has appealed this Court's judgment of invalidity in the Alkem case should be rejected, as "a pending appeal does not vitiate the preclusive effect of a trial court judgment." *Kokinda v. Pa. Dep't of Corr.*, 803 F. App'x 574, 577 (3d Cir. 2020).

More importantly, Bionpharma would be prejudiced by a delay in disposing of Azurity's now-meritless patent infringement claims, as Azurity is using those meritless claims to damage Bionpharma's commercial relationships, including by suing Bionpharma's suppliers,[12] and by demanding that they cutoff supply of Bionpharma's ANDA product or risk company-crippling damages awards. As an example, Azurity's Executive Chairman has been calling the CEO of Novitium's parent threatening that, if Novitium does not stop supplying Bionpharma with its ANDA product, Azurity will seek from Novitium tens of millions of dollars in infringement

[12] *See Azurity Pharm., Inc. v. CoreRx, Inc.*, C.A. No. 21-1522-LPS (D. Del.) D.I. 1, Compl.; *Azurity Pharm., Inc. v. CoreRx, Inc.*, C.A. No. 21-2515-VMC-SPF (M.D. Fla.) D.I. 1, Compl.; *Azurity Pharm., Inc. v. CoreRx, Inc.*, C.A. No. 22-784-SDM-AAS (M.D. Fla.) D.I. 1, Compl.; Novitium suit D.I. 1, Compl.

damages because, according to Azurity, Bionpharma itself will not be able to satisfy a damages award in these cases.[13]

As demonstrated above, this Court just found in the Alkem case that the subject matter of the asserted claims of the Third Wave Patents is obvious and not described in the common specification, and Azurity is estopped from contesting the invalidity of those claims in these suits. Bionpharma should not have to wait until the close of discovery to dispel the cloud of meritless litigation that threatens its supplier and customer relationships.

2. At the Very Least, Azurity's Patent Claims Should Be Stayed

If for some reason the Court decides that Bionpharma should not be granted leave to move for summary judgment on collateral estoppel grounds at this time, Bionpharma respectfully submits that Azurity's infringement claims should be severed and stayed pending resolution of Azurity's appeal in the Alkem case. While Bionpharma does not believe this would be a sufficient alternative to summary judgment, it would nevertheless be preferable to proceeding with fact discovery on claimed subject matter that this Court has already determined is obvious and not adequately described. If the Court prefers, Bionpharma will file a formal motion to stay.

B. Azurity's Proposed Schedule Is Impossible to Comply With

Azurity's proposed schedule leaves approximately ***two months*** for the parties to: (1) search for, review, and produce antitrust documents, which may amount to tens, if not hundreds, of thousands of pages of documents; (2) respond to antitrust written discovery; (3)

[13] At the Court's request, Bionpharma will promptly submit a declaration from a corporate representative attesting to this fact.

complete patent discovery; and (4) take and defend approximately ***26 depositions***.[14] This is simply nonsensical and apparent attempt to encourage the Court to "split the baby" between the parties' proposed dates, which should be rejected.

First, any suggestion from Azurity that the parties have essentially completed patent discovery is incorrect.[15] Azurity still has yet to produce documents critical to Bionpharma's patent case, including certain patent damages documents (such as licenses for other comparable drug products), the settlement agreement it entered into with Amneal[16] granting Amneal rights to market an authorized generic, and documents pertaining to Bionpharma's licensing/first sale/patent exhaustion defenses.[17] In addition, shortly before the Court stayed these actions, Azurity supplemented its Rule 26(a)(1) disclosures to identify additional categories of information it intends to rely on to prove its case, and Bionpharma will need discovery on those new categories. *Compare*, D.I. 243-3, *with* D.I. 243-4. And while Azurity has served its Notice of Rule 30(b)(6) deposition of Bionpharma, which identifies 70 topics, Bionpharma still has yet

[14] Azurity has noticed up 7 depositions of Bionpharma witnesses it intends to take, including a Rule 30(b)(6) deposition of Bionpharma on no less than 70 topics (D.I. 209, 224-228, 244), and Azurity has served, or will serve, no less than 7 deposition subpoenas and 7 document subpoenas to third parties (D.I. 221, 230, 215-30, 215-31, 215-32, 215-33, 215-34). Bionpharma estimates that it will likely seek to take between 10-12 fact depositions itself.

[15] Of course, if Bionpharma is granted leave to file for summary judgment as requested herein, and this Court grants summary judgment, many of the concerns raised in this paragraph become moot. Nevertheless, the parties have not exchanged any antitrust discovery, and the two months Azurity proposes is simply not enough to complete antitrust discovery.

[16] *See Silvergate Pharm., Inc. v. Amneal Pharm. LLC*, C.A. No. 19-678-LPS (D. Del.); *see also* D.I. 214, Bionpharma's Stay Mot. Opening Br. at 15-16.

[17] Although, prior to the stay entered by the Court on December 7, 2022 (D.I. 250), Bionpharma focused on a subset of deficiencies in Azurity's patent discovery responses—in order to secure discovery necessary to proceed with at least some fact depositions—Bionpharma has in no way waived its right to secure all of the patent fact discovery it has sought that Azurity has yet failed to produce (*e.g.*, discovery concerning Bionpharma's licensing defense, *see* D.I. 215, 11/9/22 Shrestha Decl. Ex. A, Bionpharma ROG No. 3; *id*. at Ex. B, Bionpharma RFP Nos. 11-14; *id*. at Ex. E, 5/2/22 Ltr. from A. Johnson at 5, 8).

to issue its Notice of Rule 30(b)(6) deposition of Azurity, and the parties have not yet even negotiated the scope of Rule 30(b)(6) depositions. Finally, as explained in Bionpharma's Opening Brief in support of its Motion to Stay with citations to the record, after telling Bionpharma that it would provide its validity contentions for the Third Wave Patents in response to Bionpharma's invalidity contentions, Azurity reneged on its promise by providing only its contentions for the '405 patent, and by belatedly alleging that Bionpharma's invalidity contentions for the '023 patent were deficient. *See* D.I. 214 at 7-8, 10-11. Bionpharma still does not have Azurity's validity contentions for the '023 patent—something Bionpharma needs to commence patent fact depositions. Bionpharma intends to try to resolve this without court-intervention by serving an amended set of invalidity contentions that attempt to address Azurity's meritless criticisms, but this will take time, including time for Azurity to finally serve its validity contentions for the '023 patent.

On the antitrust side, of course, no antitrust discovery has been exchanged between the parties; the parties still need to search for, review, and produce antitrust documents, respond to written discovery on antitrust, and take depositions. Azurity never explains how all of this is even remotely possible under its proposed schedule which allows for only 2 months to complete fact discovery, less than a quarter of what Judge Stark's Scheduling Order envisioned.

Next, Azurity's proposal of only four months for expert discovery completely ignores the scope of these cases. Bionpharma reasonably estimates that each side will likely have at least 4 experts (1-2 on patent infringement/invalidity, 1 on patent damages, and 1 on antitrust), for a total of at least 8 experts in the case. Bionpharma respectfully submits that four months to serve and respond to reports, to take depositions, and to resolve any disputes, is simply not enough. Furthermore, as explained below, Azurity's proposal that there be only two rounds of expert

reports is contrary to Judge Stark's original Scheduling Order in these cases (where the parties agreed on three rounds of reports), and is nothing more than an attempt to use scheduling to undermine Bionpharma's patent invalidity case.

Finally, Azurity's non-serious proposal ignores the obvious—that ***there will be discovery disputes*** requiring court resolution, including and especially disputes over attorney-client privilege claims that the parties will most surely make in the course of antitrust discovery. Azurity never explains how the two months it proposes for fact discovery (or the four months it proposes for expert discovery) would even account for all of the discovery that still needs to be taken and the disputes that will most certainly arise requiring this Court's assistance.

C. Bionpharma's Proposed Schedule Is Practical, Fair, and Provides the Parties with Adequate Time

The approximately 9 months Bionpharma proposes for the parties to complete fact discovery in this case is consistent with scheduling orders entered in other pharmaceutical antitrust cases in this Circuit. *See, e.g.,* Ex. B-2, *King Drug Co. of Florence, Inc. v. Cephalon, Inc.*, C.A. No. 06-2768-MSG (E.D. Pa.) D.I. 250, Scheduling Order ¶ 2 (approximately 10 month fact discovery period); Ex. B-3, *Abbott Labs v. Teva Pharm. USA, Inc.*, C.A. No. 2-1512-SLR (D. Del.) D.I. 390, Scheduling Order at 5 (approximately 1 year fact discovery period); Ex. B-4, *Takeda Pharm Co. v. Zydus Pharm. (USA) Inc.*, C.A. No. 18-1994-FLW-TJB (D.N.J.) D.I. 79, Scheduling Order (9 month fact discovery period). The approximately 9 months Bionpharma proposes provides adequate time to: (1) complete patent document production and written discovery; (2) collect, review, and produce antitrust documents; (3) exchange written antitrust discovery; and (4) take and complete the approximately 26 depositions that the parties have noticed or will notice. It will also give the parties necessary time to negotiate the scope of Rule 30(b)(6) depositions. Furthermore, 9 months for fact discovery is imperative given the strong

likelihood that there will be a number of discovery disputes requiring judicial attention, especially including as to resolution of privilege claims in connection with Bionpharma's antitrust counterclaims.

Moreover, to date, Azurity has not provided Bionpharma with its position on consolidation of the Novitium suit; Bionpharma respectfully submits that consolidation would promote judicial economy, and Bionpharma and Novitium intend to move for consolidation. Should the Novitium case be consolidated with the instant Third Wave Suits, and should Azurity be allowed to proceed with its invalid patent claims, time will need to be built into the fact discovery period to allow for preliminary patent exchanges that need to take place pursuant to Delaware Default Standard for Discovery Rules 3 and 4, and for service of and responses to discovery requests concerning Novitium.

Finally, Bionpharma respectfully submits that the 8 months it has included in its proposed schedule for expert discovery is appropriate given that these cases comprise patent, antitrust, and damages claims that will require at least 8 experts to serve and respond to reports and to testify by deposition. It also provides the parties and the Court ample time to resolve any expert discovery disputes that arise.

D. The Court Should Order Three, Not Two, Rounds of Expert Reports

Azurity's proposal of only two rounds of expert reports marks a complete reversal from its previous position on the appropriate number of rounds of expert reports in these cases. In connection with the original Scheduling Order entered by Judge Stark in these actions, the parties ***both proposed and agreed to***, and Judge Stark ordered, three rounds of expert reports. *See* D.I. 126, Scheduling Order at 8. Azurity has provided Bionpharma with no explanation as to why it now wants to depart from this agreement embodied in the original Scheduling Order.

Azurity's newfound interest in only two rounds of expert reports appears to be an attempt to undermine Bionpharma's patent defenses. Specifically, the patent side of these cases is predominantly (but not only) an invalidity case, as evinced by the preliminary injunction proceedings that took place between August-November of 2021 in the 21-1286 case (involving the '023 patent), where Bionpharma relied solely on its invalidity defenses to successfully show that Azurity did not have a likelihood of success on the merits. *See generally* D.I. 38, Bionpharma's TRO/PI Mot. Opp'n.[18] Now, by switching gears and proposing only two rounds of expert reports, Azurity apparently is trying through a scheduling dispute to deprive Bionpharma's invalidity expert of the opportunity to reply to Azurity's invalidity expert's rebuttal opinions.[19] The Court should reject Azurity's proposal—the parties had previously agreed to, and Judge Stark ordered, three rounds of expert reports to allow a party that bears the burden on an issue to serve a report that replies to rebuttal opinions from the opposing side's experts. There is absolutely no reason to deviate from this, and doing so would prejudice Bionpharma's invalidity defenses—Bionpharma's primary patent defenses in these cases—by giving Azurity's experts the last word on invalidity.

III. CONCLUSION

Bionpharma respectfully requests that the Court (1) grant it leave to move for summary judgment on patent claims solely on the basis of collateral estoppel arising from this Court's

[18] *See also* D.I. 96, 11/10/21 Hr'g Tr. 60:1-9 ("THE COURT: You have not articulated any noninfringement defenses to this point for purposes of today, including the preliminary injunction. Should I assume that you concede infringement? MR. ALUL: I wouldn't make that assumption, Your Honor. I think for now for purposes of — we're not even, we're not even past the pleading stage yet. But I think for purposes of the currently pending motions, we're not asserting non-infringement right now.").

[19] As the party who bears the burden of proof on invalidity, Bionpharma must serve an opening report on invalidity.

Judgment of invalidity entered in the Alkem case, and (2) adopt and enter Bionpharma's proposed schedule.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Megan E. Dellinger

Jack B. Blumenfeld (#1014)
Megan E. Dellinger (#5739)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@morrisnichols.com
mdellinger@morrisnichols.com

Attorneys for Plaintiff Azurity Pharmaceuticals, Inc.

PHILLIPS, MCLAUGHLIN & HALL, P.A.

/s/ Megan C. Haney

John C. Phillips, Jr. (#110)
Megan C. Haney (#5016)
1200 North Broom Street
Wilmington, DE 19806
(302) 655-4200
jcp@pmhdelaw.com
mch@pmhdelaw.com

Attorneys for Defendant Bionpharma Inc.

February 21, 2023